

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,  
AND IRBESARTAN PRODUCTS  
LIABILITY LITIGATION**

**This Document Relates to All Actions**

MDL No. 2875

Honorable Robert B. Kugler,  
District Court Judge

Honorable Karen M. Williams,  
Magistrate Judge

Honorable Thomas Vanaskie  
(Ret.), Special Discovery Master

**THE ZHP PARTIES' BRIEF IN OPPOSITION TO PLAINTIFFS' MOTION  
TO COMPEL PRODUCTION OF DOCUMENTS WITHHELD AS CHINESE  
STATE SECRETS AND IN SUPPORT OF CROSS-MOTION FOR  
PROTECTIVE ORDER**

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## I. INTRODUCTION

As factual discovery comes to a close in this matter, Plaintiffs continue to demonstrate that they are singularly focused on the continuous harassment of the ZHP Parties<sup>1</sup> through never-ending and disproportionate discovery demands. The pending motion—in which Plaintiffs seek to compel the production of twenty-three (23) documents<sup>2</sup> that are barred from production due to Chinese state secrecy laws—is no exception.

Plaintiffs have submitted a motion that is completely devoid of the relevant legal analysis or any expert analysis of the complex issues of Chinese law that are at the heart of this dispute. Indeed, Plaintiffs are now so bold as to submit a motion without any meaningful discussion of the potential *civil and criminal penalties* ZHP and its employees in China may face if the documents at issue are disclosed. Instead, Plaintiffs’ motion to compel the production of these documents rests on pure speculation about Chinese law and mischaracterizations of the documents at issue.

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<sup>1</sup> Three U.S. companies affiliated with ZHP have been named as defendants in this lawsuit, Huahai US, Inc. (“Huahai US”), Princeton Pharmaceutical, Inc. (“Princeton”), and Solco Healthcare U.S., LLC (“Solco”). Together, these four ZHP-related entities are referred to herein as the “ZHP Parties.”

<sup>2</sup> Although Plaintiffs in some portions of their brief state that they seek to compel “thirty-six non-duplicative documents,” they have only listed twenty-three documents in their Memorandum of Law. See [Dkt. 1231](#) at 6-14. Accordingly, the ZHP Parties will treat Plaintiffs’ motion as seeking to compel those twenty-three documents.

As set forth herein, Plaintiffs' motion should be denied because:

- Despite the fact that this Court has expressly stated that it is “going to apply the *Aerospatiale*<sup>3</sup> and *Richmark*<sup>4</sup> factors” to decide this matter (see 3-16-21 Hrg. Tr. at 27:11-13), Plaintiffs have failed to address these factors in any meaningful way;
- Each and every *Aerospatiale* and *Richmark* factor weighs in favor of the ZHP Parties, including but not limited to the fact that the documents at issue are not vital to Plaintiffs' claims; and
- Plaintiffs have failed to present or even cite to any expert opinion or analysis in support of their newest argument that the documents at issue are not subject to Chinese state secrecy laws, and have utterly failed to rebut the expert analysis proffered by Ms. Xueyu Yang on behalf of the ZHP Parties.

## II. PERTINENT FACTUAL AND PROCEDURAL BACKGROUND

At issue are fourteen (14) documents that the ZHP Parties have provided to Plaintiffs in redacted form and nine (9) documents that have been withheld in their entirety because they are barred from production under the laws of the People's Republic of China (“PRC”). The relatively small universe of documents at issue -- just .00657% of the ZHP Parties' production of more than 350,000 documents -- is a direct result of the ZHP Parties' significant efforts and expenditures undertaken to ensure that the ZHP Parties' production was as fulsome as possible, while at the same time complying with Chinese law.

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<sup>3</sup> *Societe Nationale Industrielle Aerospatiale v. United States Dist. Ct., S.D. Iowa*, 482 U.S. 522 (1987).

<sup>4</sup> *Richmark Corp. v. Timber Falling Consultants*, 959 F.2d 1468 (9th Cir. 1992).

Indeed, ZHP engaged three different China-based law firms to review the data collected in response to Plaintiffs' document requests to determine if the documents were subject to China's state secrecy laws. *See* Exhibit A at ¶¶ 14-15 (Declaration of Ms. Xueyu Yang "Yang Declaration"). Specifically, two separate China-based law firms performed a first level review of documents collected in response to Plaintiffs' document requests to determine if the documents were subject to China's state secrecy laws. *See* Exhibit A at ¶ 14 (Yang Declaration). These firms logged the documents that they determined were prohibited from disclosure under PRC law. *See* Exhibit A at ¶ 14 (Yang Declaration). After this first-level review, the Hui Zhong law firm then performed a second level review of the documents logged during the first level review as a quality check of the work performed by the other two law firms in order to ensure that the ZHP Parties produced as much information as possible in this litigation while at the same time complying with Chinese law. *See* Exhibit A at ¶ 15 (Yang Declaration).

Initially, on December 30, 2020, the ZHP Parties' State Secret Review Log ("SSR Log") was served on Plaintiffs and included 335 documents. After the second level review was complete, only 91 documents out of the more than 350,000 documents that ZHP produced were withheld or redacted on the basis of China's state secrecy laws.

To date, the parties have spent hours meeting and conferring about the SSR Log. The first meet and confer occurred on March 5, 2021 and was abruptly ended by Plaintiffs when they concluded the documents were relevant despite being reminded that the test for production is not relevancy but instead the multi-factor test required under United States Supreme Court precedent, as discussed below. *See infra* Section III. On March 9, 2021, Plaintiffs then requested that the Court strike ZHP’s entire SSR Log. *See* [Dkt. 1011](#). This Court ordered oral argument on the issue of the adequacy of ZHP’s Chinese State Secrecy Log for March 16, 2021. *See* [Dkt. 1021](#). On March 15, 2021, the ZHP Parties submitted a letter opposing Plaintiffs’ claim that the SSR Log be stricken. *See* [Dkt. 1027](#). Following oral argument, the Court ordered that the ZHP Parties and Plaintiffs meet and confer “on the record” with respect to the possible production of documents on the SSR Log and file a status report on the efforts to resolve the disputes concerning documents withheld on the basis of Chinese State Secret privacy laws. *See* [Dkt. 1034](#). At oral argument, the Court noted it was “favorably impressed by the level of review that the documents went through . . . *it shows that [the ZHP Parties are] really operating in good faith here* and I did want to note that.” 3-16-21 Hrg. Tr. at 38:17-18 (emphasis added).

Prior to the meet and confer, the ZHP Parties wrote to Plaintiffs informing them that of the 91 documents on the SSR Log, there were only thirty-six non-duplicative documents. *See* Exhibit B (ZHP’s 3-23-21 Email to Plaintiffs). On



March 26, 2012, Plaintiffs and ZHP met and conferred for four and a half hours and discussed each non-duplicative document on the SSR Log. *See* Exhibit C (3-26-21 Meet and Confer Tr.). The ZHP Parties' Chinese counsel participated in the meet and confer and answered all questions asked by Plaintiffs that could be answered without violating state secret law. Notably, Plaintiffs did not have an expert in Chinese law or a China-based law firm attend the meet and confer.<sup>5</sup>

Following the meet and confer, only 28 documents remained in dispute. On April 1, 2021, the ZHP Parties provided clarification to Plaintiffs as to the nature of the duplicative documents on the SSR Log. *See* Exhibit D (ZHP's 4-1-21 Email to Plaintiffs). Of the twenty-three (23) documents still in dispute, the ZHP Parties have provided Plaintiffs with fourteen (14) documents in redacted form. *See* Exhibit E (Log of 14 Redacted Documents). Accordingly, only nine (9) documents are being withheld in their entirety on the basis of state secrecy laws. *See* Exhibit E (Log of 9 Withheld Documents).<sup>6</sup>

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<sup>5</sup> In fact, based on Plaintiffs' statements to the Court during the March 16, 2021 hearing, it is clear that Plaintiffs have not retained anyone to advise them on Chinese law. *See* 3-16-21 Hrg. Tr. at 30:20-24 (MR. SLATER: "We're not being advised by any outside lawyers. We think that our team of leadership can read the state secret laws, read the case law and understand what it means. ***If we determine to retain somebody, we will and we'll bring them to the call.***" (emphasis added)).

<sup>6</sup> Plaintiffs were provided with complete metadata on the state secret logs; however, in order to provide the Court with the logs in an easily viewable form, certain fields have been omitted from Exhibit D and Exhibit E.

### III. ARGUMENT

United States Supreme Court precedent requires this Court to carefully analyze the factors set forth in *Societe Nationale Industrielle Aerospatiale v. United States Dist. Ct., S.D. Iowa*, 482 U.S. 522 (1987) in deciding whether Chinese state secret laws excuse noncompliance with discovery rules. 482 at 544 n.28. Indeed, this Court has expressly stated that it is “going to apply the *Aerospatiale* and *Richmark*<sup>7</sup> factors . . . to decide this.” See 3-16-21 Hrg. Tr. at 27:11-13. Although Plaintiffs acknowledge this standard and list the *Aerospatiale* factors in their Memorandum of Law, ***they fail to analyze a single factor as it relates to the documents at issue*** (see [Dkt. 1231](#) at 15-16). Instead, Plaintiffs argue that because the ZHP Parties have not made a showing of the “present danger” of the consequences of production, the documents must be produced. See [Dkt. 1231](#) at 16-17. However, this “present danger”<sup>8</sup> test now championed by Plaintiffs has no basis in law, and the factors set

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<sup>7</sup> *Richmark Corp. v. Timber Falling Consultants*, 959 F.2d 1468.

<sup>8</sup> Plaintiffs rely on *Autodesk, Inc. v. ZWCAD Software Co.* in claiming that the relevant inquiry is simply whether the withholding party faces “present danger” if the protected documents are produced. See [Dkt. 1231](#) at 16-17. However, this reliance is misplaced, as rather than applying any type of “present danger” standard, the Court in *Autodesk* expressly applied the *Aerospatiale* factors in reaching its holding. No. 5:14-cv-01409, 2015 WL 1928184, at \*1, \*3-4 (N.D. Cal. Mar. 27, 2015) (“ZWSOFT has not shown that a genuine risk of liability under Chinese law ***or other factors*** justify the additional protective measures it seeks[.]”)) (emphasis added).

forth in *Aerospatiale* and *Richmark* factors weigh decidedly in favor of the ZHP Parties.

Plaintiffs’ motion also is unsupported by any expert testimony on Chinese law. Well-established legal principles provide that experts are usually needed to prove foreign law and, absent that proof, a party’s arguments rely on speculation and guesswork.<sup>9</sup> As set forth in Ms. Yang’s declaration, Plaintiffs’ motion fundamentally misinterprets Chinese state secret law by injecting Plaintiffs’ “own evaluation of what they believe China’s national interests should be, rather than relying on what the government itself has stated its national interests actually are.” *See* Exhibit A at ¶ 25. In addition, Plaintiffs repeatedly state that Article 2 of the Guarding State Secrets Law only applies to “matters that have a *vital* bearing on State security and national interests.” *See, e.g., Dkt. 1231* at 1. However, the law (as written in Chinese) does not use the Chinese word for “vital,” nor do the Chinese words used even implicate the same meaning as the English word “vital.” *See* Exhibit A at 4 n.1. Instead, an accurate translation of that provision of Article 2 actually states: “[s]tate secrets refer to **matters which relate to the national security and interests** as

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<sup>9</sup> *See, e.g., Autodesk*, 2015 WL 1928184, at \*4 (ruling against the defendant because of its “failure to respond with expert testimony or other authority that contradicts [the] assertions [of the plaintiff’s expert in Chinese law],” such that the defendant offered only “unsubstantiated claims” about “Chinese state secrecy laws”).

*determined under statutory procedures and to which access is vested in a limited scope of persons during a given period of time.” Id. at 4.*

Because every *Aerospatiale* factor weighs in favor of the ZHP Parties, and because Plaintiffs are unfit to interpret and apply Chinese state secret law (as opposed to Ms. Yang), the Court should deny Plaintiffs’ motion.

**A. Plaintiffs’ Motion to Compel Should Be Denied Because the *Aerospatiale* Factors Weigh in favor of Allowing ZHP to Withhold the Documents at Issue from Production**

In *Aerospatiale*, the United States Supreme Court set forth a careful balancing test for courts to use when deciding whether to order the production of discovery that is barred by the laws of a foreign county. *Aerospatiale*, 482 U.S. at 544, n.28. Specifically, the court must consider:

1. “[T]he importance to the . . . litigation of the documents or other information requested;”
2. “[T]he degree of specificity of the request;”
3. “[W]hether the information originated in the United States;”
4. “[T]he availability of alternative means of securing the information;” and
5. “[T]he extent to which noncompliance with the request would undermine important interests of the United States, or compliance with the request would undermine important interests of the state where the information is located.”

*Id.* As the Supreme Court explained in *Aerospatiale*, this list is not exhaustive and courts often consider two other factors:

6. The extent and nature of the hardship on the party from whom discovery is sought; and
7. The good faith of the party resisting discovery.

*Id.*; see also *Richmark Corp. v. Timber Falling Consultants*, 959 F.2d 1468, 1477-80 (9th Cir. 1992) (analyzing both the hardship and good faith factors).

In setting forth this balancing test, the United States Supreme Court cautioned American courts to “exercise *special vigilance* to protect foreign litigants[.]” *Aerospatiale*, 482 U.S. at 546 (emphasis added). In recognition of the “disadvantageous position” “that unnecessary, or unduly burdensome, discovery may place [foreign litigants] in[.]” the United States Supreme Court mandated that courts “should therefore *take care to demonstrate due respect for any special problem confronted by the foreign litigant* on account of its nationality or the location of its operations, and for any sovereign interest expressed by a foreign state.” *Id.* (emphasis added).

Taking this precedent and guidance into account, federal courts have applied the *Aerospatiale* factors and ruled that documents should not be produced in light of foreign laws precluding that discovery. In particular, Judge Scheindlin has applied the *Aerospatiale* factors in the face of Chinese secrecy laws and ultimately precluded

“the production of confidential regulatory documents *created by the Chinese government* whose production [wa]s clearly prohibited under Chinese law[.]” *Wultz v. Bank of China Ltd.*, 910 F. Supp. 2d 548, 556 (S.D.N.Y. 2012) (emphasis in original) (Scheindlin, J.). Under the facts presented in that case, Judge Scheindlin recognized and protected China’s sovereign interest in accordance with the United States Supreme Court precedent. *See id.* (recognizing that an order which would require the production of the regulatory documents of a foreign government may violate principles of international comity and sovereignty).

As set forth below, this Court should deny Plaintiffs’ request for the production of these documents because each factor weighs in favor of allowing the ZHP Parties to withhold or produce with redactions the twenty-three (23) documents at issue.

1. The Twenty-Three Documents at Issue are Not Vital to Plaintiffs’ Claims

The first factor the Court must consider is the importance of the foreign discovery requested. When the information sought “does not stand or fall on the present discovery order” and is “in a sense cumulative” courts are generally unwilling to override foreign secrecy laws. *See In re Westinghouse Elec. Corp. Uranium Conts. Litig.*, 563 F.2d 992, 999 (10th Cir. 1977) (finding the trial court erred in holding corporation in contempt and imposing sanctions for its failure to comply with discovery order). In stark contrast to the discovery standards set forth

in the Federal Rules of Civil Procedure, the requested documents must be ***more than relevant*** – they must be “***vital***” or “***crucial***” to the claims in the litigation.<sup>10</sup> *See, e.g., Reinsurance Co. of Am. v. Administratia Asigurarilor de Stat (Admin. of State Ins.)*, 902 F.2d 1275, 1279-81 (7th Cir. 1990) (holding plaintiff was not entitled to discover information considered “service secrets” under Romanian law where disputed materials were not relevant to the case-in-chief); *In re Activision Blizzard, Inc. Stockholder Litig.*, 86 A.3d 531, 544 (Del. Ch. 2014) (“This factor calls on the court to consider the degree to which the information sought is ***more than merely relevant*** under the broad test generally for evaluating discovery requests.”) (emphasis added).

Plaintiffs’ reliance on *Autodesk* to support their argument that these documents must be produced is wholly misplaced. *See* [Dkt. 1231](#) at 16. In *Autodesk*, plaintiff sued for the alleged “wholesale theft of its proprietary source code” by a Chinese company, ZWSOFT. *See Autodesk, Inc.*, 2015 WL 192818 at \*1. ZWSOFT’s source code data and documents were located in China, and it resisted production on the basis of Chinese state secret law. *Id.* Considering plaintiff ***could not pursue its***

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<sup>10</sup> Thus, while a document does not have to have a “***vital*** bearing on State security and national interests” to be considered a Chinese state secret as Plaintiffs incorrectly espouse ([Dkt. 1231](#) at 3), U.S. precedent does require that the documents be ***vital to the litigation*** – and more than merely relevant – in order to override Chinese state secrecy laws.

*allegations of source code theft* without inspecting ZWSoft's *source code documents*, the court ordered its production. *Id.*<sup>11</sup>

Here, unlike in *Autodesk*, Plaintiffs have not shown that any of the twenty-three (23) documents at issue are “crucial” or “vital” to this litigation. Rather, seventeen of the documents concern communications with, reports to, or report from *Chinese regulatory bodies*, (see Exhibit A, ¶¶ 26(b), 26(g)-(o), 26(q)-(r), 26(t)-(w) (describing PRINBURY00148044; ZHP02605629; ZHP02608269; ZHP02608270; ZHP02608279; ZHP02613610; ZHP02615167; ZHP02621763; ZHP02622051; ZHP02622054; ZHP02622057; ZHP02622059; ZHP02636529; ZHP02636533; ZHP02636534; ZHP02649530), while four documents contain meeting minutes with *Chinese governmental bodies* such as the Chinese Center for Drug Evaluation (“CDE”), the Taizhou Medical Product Administration, the Zhejiang Medical Products Administration, and the National Medical Products Administration. See Exhibit A, ¶¶ 26(a), 26(c), 26(e)-(f) (describing PRINBURY00142827;

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<sup>11</sup> In a notable role reversal, the plaintiff in *Autodesk* supported its motion to compel the source code documents with expert testimony on Chinese State Secret Law, and the defendant from whom the documents were sought did not proffer any expert testimony in rebuttal. *Autodesk, Inc.*, 2015 WL 1928184, at \*4. Here, Plaintiffs do not support their motion to compel with any expert testimony or even a declaration from any lawyer in the MDL's vast Plaintiffs' counsel group who is licensed to practice law in China, or has any experience whatsoever with Chinese law. In contrast, the ZHP Parties' opposition is supported by the declaration of Ms. Xueyu Yang regarding China's state secrecy laws. See Exhibit A.



ZHP02459190; ZHP02604526; ZHP02605097). Plaintiffs fail to articulate why any of these documents that focus exclusively on the Chinese market and Chinese consumers would be vital or critical to the litigation. Notably, this entire litigation revolves around generic drugs that were sold in the *U.S.* market to *U.S.* consumers, and whether the defendants acted in accordance with the regulations enforced by the *U.S.* Food and Drug Administration (“FDA”).

The three remaining documents that do not involve reports or meeting minutes with Chinese regulatory bodies involve communications with the Chinese government that have nothing to do with the claims at issue in this litigation. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Even if the information the ZHP Parties exchanged with the Chinese government about the Chinese market were somehow relevant, Plaintiffs have conceded it would not be vital or crucial to their claims because it would be cumulative of the information the ZHP Parties exchanged with the FDA. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] As Plaintiffs further concede in their motion to compel, one of the documents they are challenging “contains information produced to every other foreign regulatory authority.” See [Dkt. 1231](#) at 11 (discussing ZHP02615167). Additionally, the ZHP Parties have produced more than *3.5 million pages of documents*, including communications with the FDA and other nations’ regulatory agencies concerning the allegations at issue in this litigation. Therefore, any information in these twenty-three (23) documents would be largely “cumulative” of the information contained within the hundreds of thousands of regulatory and other documents already within Plaintiffs’ possession.

Accordingly, this factor weighs heavily in favor of the ZHP Parties because along with being unnecessarily cumulative, these documents contain communications with Chinese regulatory authorities that are not relevant, important, or anywhere near “vital” to this litigation.

2. Plaintiffs’ Broad and Overreaching Discovery Requests are Not Specific

The second *Aerospatiale* factor requires the Court to consider the degree of specificity of the requests for foreign discovery. “Generalized searches for information, the disclosure of which is prohibited under foreign law, are discouraged.” *Richmark Corp.*, 959 F.2d at 1475. The court must look to the degree to which the foreign discovery requests are “narrowly tailored” to the claims and defenses of the litigation. *Strauss*, 249 F.R.D. at 440-41.

The discovery requests at issue here are anything but narrowly-tailored. *See* [Dkt. 328](#) (Plaintiffs’ Court approved Requests Documents Production). Plaintiffs’ Requests for Production of Documents to API and Finished Dose Manufacturing Defendants requested ***more than ninety-five categories of documents*** from the ZHP Parties, comprehensively covering their operations potentially relating to valsartan, including requests for organizational information policies, agreements with defendants, communications with defendants, ANDA and DMF files, documents pertaining to the manufacturing, testing records, regulatory correspondence, recall-related communications, and sales data, among other requests. *See* Exhibit G,

Document Requests. Documents responsive to these requests were collected in a comprehensive manner including collections of non-custodial documents as well as the application of *over 400 search terms* across *83 custodians*. *Id.*; Exhibit H, Custodian List.

These expansive requests have led to the production of over 350,000 documents totaling over 3.5 million pages. Despite this substantial volume of discovery, Plaintiffs have only introduced 457<sup>12</sup> documents at depositions, excluding translations. But even these expansive requests for production have not satisfied Plaintiffs. On April 24, 2021, Plaintiffs sent a letter to the ZHP Parties requesting *fifteen* additional categories of documents. *See* Exhibit I. In response to these requests, the ZHP Parties agreed to, among other things:

- Produce the custodial files of *seven additional custodians* based on the original 400+ search terms;
- Review the collection of *thirteen* custodians and, if necessary, supplement their production with any additional responsive, non-privileged documents; and
- Apply the following *six new search terms* across all existing and new custodians and to produce any additional responsive, non-privileged documents: Zhejiang Second Pharma, CN103613558A, Impurity K, NALCO, Hypochlorite and TC-201729.

*See* [Dkt. 1228](#).

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<sup>12</sup> Although 457 documents have been marked at ZHP party depositions, many are duplicates or translations of earlier-marked documents.

In sum, Plaintiffs’ never-ending and incredibly far-reaching requests have resulted in an enormous document production, including many documents of little relevance or materiality to this litigation. The overreach of Plaintiffs’ requests weighs strongly in favor of denying Plaintiffs’ motion to compel.

3. All Documents at Issue Originated in China and Were Collected From Individuals Located in China

The third *Aerospatiale* factor directs the Court to consider whether the information at issue originated in the United States or abroad. This factor weighs heavily in favor of nondisclosure where all of the requested information sought and the people involved in assembling it are located in a foreign country. *See Richmark Corp.*, 959 F.2d at 1475 (“The fact that all the information to be disclosed (and the people who will be deposed or who will produce the documents) are located in a foreign country weighs against disclosure, since those people and documents are subject to the law of that country in the ordinary course of business.”); *Reinsurance Co. of Am.*, 902 F.2d at 1281 (finding the court below correctly denied the motion to compel discovery where all the information which plaintiff sought was located within Romania and the office of the defendant was located within Romania).

None of the twenty-three (23) documents at issue originated in the United States, and each document was collected in China. It is undisputed that all of the custodians responsible for maintaining the information are located in China or were

located there during the time the information was collected.<sup>13</sup> As such, this factor weighs heavily in favor of nondisclosure.

4. Plaintiffs Have Alternative Means of Obtaining the Information

The Court next considers whether there are alternative means to obtaining the requested information. “If the information sought can easily be obtained elsewhere, there is little or no reason to require a party to violate foreign law.” *Richmark Corp.*, 959 F.2d at 1475; *see also CE Int’l Res. Holdings, LLC v. S.A. Mins. Ltd. P’ship*, No. 12-cv-08087, 2013 WL 2661037, at \*10 (S.D.N.Y. June 12, 2013) (denying an order to compel where the requestor could reasonably obtain the sought after information elsewhere).

As stated above (*see supra*, Section II.A.1), not only can Plaintiffs obtain the information contained in ZHP’s State Secret Review Log elsewhere, ***Plaintiffs have already obtained the relevant information, if any, contained in these documents.***

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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<sup>13</sup> Custodian Xiaodi Guo, an employee of Defendant Princeton, is no exception. Xiaodi Guo appears on the State Secret Review Log because he works in China on a regular basis, is currently residing in China, and was in China at the time the information was collected, which are the pertinent considerations for this analysis.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Additionally, the ZHP Parties have produced more than 3.5 million pages of documents, including communications with the FDA *and* other nations’ regulatory agencies concerning the allegations at issue in this litigation. Indeed, the information already provided to Plaintiffs goes *well beyond* the information provided to regulatory authorities, as it includes *internal and external* communications regarding ZHP’s root cause analyses, deviation reports, ANDA and DMF filings, the

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<sup>14</sup> Plaintiffs have attempted to use the fact that some of the background information included in communications with Chinese government agencies was also provided to the regulatory authorities of other countries to argue that the information at issue is not “secret.” See [Dkt. 1231](#) at 10. However, this fundamentally misinterprets the nature of the laws and regulations at issue, as while they are generally categorized as “secrecy” laws, the laws provide no exemption for information that may be known to others. Instead, the laws are worded broadly such that entire communications with Chinese government organs are subject to state secrecy laws. Exhibit A at ¶¶ 8-9, 12 (Declaration). Indeed, as noted in Ms. Yang’s declaration, the laws at issue allow the Chinese government to deem information a state secret *retroactively*, meaning that information may be deemed a state secret even *after* it was made publicly available. Exhibit A at ¶¶ 11 (Declaration). Further, as previously noted, the ZHP Parties have redacted, rather than fully withheld, fourteen (14) of the documents at issue in an attempt to provide as much information as possible on these documents without violating Chinese law. See Exhibit E (Log of 14 Redacted Documents).

ZHP Parties' communications with their customers regarding the impurity, and much more.

Given that these twenty-three (23) documents are not vital to Plaintiffs' case and cumulative of the information the ZHP Parties exchanged with the FDA, the ZHP Parties should not be forced to violate Chinese law and subject themselves to severe criminal and civil penalties. Accordingly, this factor weighs heavily in favor of nondisclosure.

5. The Balance of National Interests Favor Nondisclosure

Next, the Court must balance the interests of each nation in requiring or prohibiting disclosure of the requested information, which is a factor often given great weight by courts. *See Richmark Corp.*, 959 F.2d at 1476 (referring to this factor as "the most important factor"). In balancing the interests of American and foreign courts, American courts have given deference to a foreign nation's interest in the considerable value they assign to their confidentiality and privacy. *See, e.g., Reinsurance Co.*, 902 F.2d at 1279-81 (finding Romania's interest in its "service secrets" outweighed the interests of the United States given the scope of Romania's laws and the severe penalties for violations); *White v. Kenneth Warren & Son, Ltd.*, 203 F.R.D. 369, 375 (N.D. Ill. 2001) (finding England's "interests in confidentiality" outweighed the American court's interest in the production of documents that were deemed confidential under English law). The extent of a foreign nation's interest in



protecting its “secrets” is evidenced primarily by the scope of its protective laws, the strict enforcement of those laws, and the possibilities of severe sanctions and penalties. *See Reinsurance Co.*, 902 F.2d at 1280.

China greatly values confidentiality afforded to the information and communications of its governmental entities. *See* Exhibit A at ¶¶ 7-8, 28 (Yang Declaration). China’s interest in protecting this information is evidenced by the Chinese laws that impose severe criminal and civil penalties on any individual who transmits “state secrets” outside of the country. *See* Exhibit A at ¶ 28 (Yang Declaration). The penalties for transmitting Chinese state secrets outside of China “rang[e] from administrative fines to a criminal sentence” including “imprisonment up to seven years.” *See* Exhibit A at ¶ 28 (Yang Declaration). As such, ZHP’s unlawful disclosure of these documents may subject ZHP and its employees to administrative and criminal penalties. *See* Exhibit A at ¶ 28 (Yang Declaration).

While this Court undeniably has an interest in upholding its discovery rules and orders, ZHP should not suffer because of China’s interest in protecting the confidentiality of its government communications and information. China’s confidentiality and state secrecy interests are also more immediate and compelling than any other interest in this litigation given the nature of Plaintiffs’ claims, ***which are wholly unrelated to any action of the Chinese government or any Chinese regulatory authority.*** Moreover, as described below (*see infra*, Section II.A.7), the

ZHP Parties have made good faith efforts, and will continue to make good faith efforts, to comply with this Court's discovery orders. Accordingly, this factor weighs in favor of permitting ZHP to withhold the documents at issue from production.

6. ZHP will Face Extreme Hardship if Ordered to Produce These Documents

The extent and nature of the hardship that the discovery request is likely to have on the foreign entity is another factor for this Court to consider. "If compliance with a discovery request would subject the party on whom compliance is sought to liability or sanctions, this factor will weigh against compelling disclosure." *CE Int'l Res. Holdings, LLC*, 2013 WL 2661037, at \*15.

As described above (*see supra*, Section II.A.5), and described in detail in the declaration of Ms. Yang (*see* Exhibit A at ¶ 28 (Yang Declaration)), China imposes severe criminal and civil penalties on individuals who violate its state secrecy laws. While the ZHP parties are actively seeking permission from the Chinese government to produce the documents at issue (*see* Exhibit A at ¶¶ 21-22 (Yang Declaration)), the ZHP Parties have been extremely transparent with this Court and Plaintiffs in that there is no guarantee that the Chinese government will allow ZHP to produce these documents. *See* 3-16-21 Hrg. Tr. at 11:7-12. If the ZHP Parties disclose these documents without the Chinese government's permission, both ZHP and its employees will be at risk of facing severe civil and criminal penalties. *See* Exhibit

A at ¶¶ 13, 29 (Yang Declaration). Accordingly, this factor weighs heavily in favor of permitting ZHP to withhold the documents at issue.

7. The ZHP Parties Have Made, and Continue to Make, Good Faith Attempts Comply with The Court's Discovery Orders

Whether the party that opposes foreign discovery has made a good faith effort to comply with the discovery order is another factor considered by the courts. *See CE Int'l Res. Holdings, LLC*, 2013 WL 2661037, at \*16. Here, there can be no doubt that the ZHP Parties have made a good faith effort to comply with their discovery obligations. As acknowledged by this Court, “I am favorably impressed by the level of review that the documents went through . . . ***it shows that you're really operating in good faith here*** and I did want to note that.” 3-16-21 Hrg. Tr. at 38:17-18 (emphasis added). Indeed, ZHP has met its discovery obligations throughout this litigation, despite the tremendous burden being a foreign defendant attempting to meet incredibly wide-ranging discovery demands ***in the midst of a global pandemic***.

As set forth in the declaration of Ms. Yang, since initially serving their state secret logs on December 30, 2020, the ZHP Parties have worked with three Chinese law firms to continually streamline the population of state secret documents. *See* Exhibit A at ¶¶ 14-15 (Yang Declaration). Following these careful attempts to winnow the withheld document population, counsel for the ZHP Parties, including ZHP's China-based counsel, met and conferred for four and a half hours with Plaintiffs answering any questions they had about the documents at issue, provided

that they did not violate state secret law. *See* Exhibit C (3-26-21 Meet and Confer Tr.). Through this meet and confer, ZHP’s China-based counsel provided information on each of the documents, sufficient to winnow the contested document population to the twenty-three (23) documents currently subject to Plaintiffs’ motion.

The ZHP Parties have made every effort to comply with their discovery obligations while also abiding by Chinese law, even going so far as to ask Chinese authorities to permit them to produce the documents at issue. Accordingly, this seventh and final factor, as with the other *Aerospatiale* and *Richmark* factors, weighs in favor of the ZHP Parties.

**B. There Is No Basis For Plaintiffs’ Claim That The Documents at Issue Do Not Contain State Secrets**

In a transparent attempt to avoid the applicable legal standard on this issue—*i.e.*, the *Aerospatiale* and *Richmark* factors—the thrust of Plaintiffs’ latest argument is that the 23 documents at issue “do not contain Chinese state secrets,” an analysis which is based on their own, wholly-unsupported, interpretation of Chinese law. *See* [Dkt. 1231](#). As a matter of general principle, Plaintiffs are not equipped to opine on China’s state secrecy laws. “[J]udges expect adequate expert testimony on foreign law and the failure to produce it may be quite damaging to a litigant’s case.” 9A Charles A. Wright & Arthur R. Miller, *Fed. Prac. & Proc. Civ.* § 2444 Proof of Foreign Law (3d ed.). Although “courts may do their own research in order to

ascertain foreign law” under Federal Rule of Civil Procedure 44.1, “expert testimony accompanied by extracts from foreign legal materials has been and will likely continue to be the basic mode of proving foreign law.” *Universe Sales Co. v. Silver Castle, Ltd.*, 182 F.3d 1036, 1038 (9th Cir. 1999).

The principle that experts on foreign law provide the primary evidence of foreign law applies to issues arising in a motion to compel. For example, in *Golden Trade v. Lee Apparel Co.*, 143 F.R.D. 514 (S.D.N.Y. 1992), the district court declined the defendants’ motion to compel on the basis of plaintiffs’ unrebutted expert affidavit on foreign law. The court reasoned that “defendants were free to proffer their own version of Norwegian law if they disagreed with [the plaintiffs’ expert’s] interpretation or if they had a basis for arguing that Norwegian law . . . would not justify invocation of a privilege on the facts presented.” *Id.* at 524. The court concluded that “[s]ince defendants have refrained from doing so, I decline to question what is, on its face, uncontradicted testimony as to both the state of Norwegian law and the facts relevant to the application of that law.” *Id.*

Similarly, in *Universe Sales*, the parties filed cross-motions for summary judgment, with the plaintiff arguing that Japanese trademark law applied and the defendant arguing that Japanese contract law applied. *Universe Sales*, 182 F.3d at 1037. The defendant submitted an expert declaration on Japanese law, which concluded that Japanese contract law should apply. *Id.* The plaintiff did not rebut the

defendant's expert declaration with its own expert. *Id.* Nonetheless, the district court granted the plaintiff's motion for summary judgment and denied the defendant's. *Id.* On appeal, the Ninth Circuit reversed the district court, and entered summary judgment for the defendant. The Ninth Circuit reasoned that "[b]ecause the Kamiya declaration stands as an unrebutted presentation and interpretation of Japanese law, the district court erred in granting summary judgment to [the plaintiff]." *Id.* at 1038.

In *Schultz v. Royal Caribbean Cruises, Ltd.*, 465 F. Supp. 3d 1232 (S.D. Fla. 2020), *motion to certify appeal denied*, No. 18-24023-CIV, 2020 WL 4905434 (S.D. Fla. July 22, 2020), the district court addressed a dispute over the application of foreign law in considering cross-motions for summary judgment. The plaintiff submitted expert testimony on Maltese law. *Id.* at 1260. The defendant, however, only "t[ook] issue with Plaintiff's experts." *Id.* The district court chastised the defendant for this omission: "Making matters worse, Defendant never relies on a single piece of expert testimony on how to interpret and apply Maltese law." *Id.* at 1261. Instead, the defendant simply adopted "the legal principles in Plaintiff's expert report but then disavow[ed] how those experts applied them." *Id.* The district court explained that "[t]his sort of legal gymnastics is entirely unhelpful because it leaves the Court with little to determine . . . how to then apply the legal principles of a foreign state." *Id.*

The court reasoned that, “in the absence of any competing expert testimony,” the defendant’s opposition to the application of foreign law by the plaintiff’s foreign experts amounted to mere “speculation” and “guesswork.” *Id.* at 1262. Thus, the court ruled that it “fail[ed] to see, given the unique question presented, how we can . . . determine whether Plaintiff’s experts misapplied that analysis [of Maltese law] without any competing expert evidence.” *Id.* The court accordingly granted the plaintiff’s motion for summary judgment as to applicability of the foreign law exception to the ADA and denied the defendant’s cross-motion.

Here, Plaintiffs admitted well in advance of the motion that they do not oppose the analysis of Ms. Yang with their own expert in Chinese law: “***We’re not being advised by any outside lawyers.***” 3-16-21 Hrg. Tr. at 30:20-21 (emphasis added). Instead, Plaintiffs merely will “read the state secret laws.” *Id.* at 30:21-22. Because Plaintiffs failed to retain an expert, Plaintiffs’ counsel had to ask Ms. Yang during the March 26, 2021 meet and confer about Chinese State Secrets Law in an effort “to make sure I was reading all the laws correctly.” Exhibit A (3-26-21 Meet and Confer Tr.) at 14:6-7.

In other words, just as in *Schultz*, Plaintiffs’ motion to compel “never relies on a single piece of expert testimony on how to interpret and apply [Chinese] law,” and simply adopts “the legal principles [of the ZHP Parties’ expert] but then disavows how [Yang Xueyu] applied” those principles. *Schultz*, 465 F. Supp. 3d at

1261. Therefore, as in *Schultz*, “in the absence of any competing expert testimony,” Plaintiffs’ motion to compel relies on their own “speculation” and “guesswork” as to China’s state secrecy laws, and leaves this Court with no basis to “determine whether [the ZHP Parties’] expert[] misapplied” Chinese law. *Id.* at 1262.

This case is also similar to the issue in *Universe Sales*, where the defendant, with the support of an expert declaration, argued that Japanese contract law applied, and the plaintiff, without an expert, argued that it did not. *See Universe Sales*, 182 F.3d at 1037. The Ninth Circuit reversed the district court’s grant of summary judgment in favor of the plaintiff, and entered its own order granting summary judgment for the defendant, “[b]ecause the [defendant’s expert’s] declaration stands as an unrebutted presentation and interpretation of Japanese law.” *Id.* at 1038. Here, Ms. Yang’s declaration “stands as an unrebutted presentation and interpretation of [Chinese] law,” and, consequently, Plaintiffs’ motion to compel fails.

Finally, Plaintiffs’ motion to compel suffers from the same fatal flaw that doomed the motion to compel in *Golden Trade*. Here, as in *Golden Trade*, Plaintiffs have had months to find their own expert and “were free to proffer their own version of [Chinese] law if they disagree[] with [Yang Xueyu’s expert] interpretation or if they ha[ve] a basis for arguing that [Chinese] law . . . would not justify invocation of a privilege on the facts presented.” *Golden Trade*, 143 F.R.D. at 524. As with the losing party in *Golden Trade*, Plaintiffs “have refrained” from proffering their own



expert, and so the Court should “decline to question what is, on its fact, uncontradicted testimony” by Yang Xueyu “as to both the state of [Chinese] law and the facts relevant to the application of that law.” *Id.*

Plaintiffs are not experts in Chinese law. They have failed to proffer an expert or any other evidence of Chinese law to oppose the declaration of Ms. Yang. Therefore, this Court should deny Plaintiffs’ motion to compel the production of the twenty three (23) documents at issue.

#### IV. CONCLUSION

The Court should deny Plaintiffs’ motion to compel. Each and every *Aerospatiale* and *Richmark* factor weighs heavily in favor of denying Plaintiffs’ motion to compel. Moreover, the ZHP Parties’ opposition is supported by an expert in Chinese law, whereas Plaintiffs’ motion is based entirely on the speculation and guesswork of American counsel.

Plaintiffs have failed to cite ***a single case*** in which a court granted a motion to compel where, as here, the *Aerospatiale* factors overwhelmingly weighed in favor of the party subject to foreign blocking statutes. Indeed, granting Plaintiffs’ motion in the circumstances of this case—*i.e.*, where Plaintiffs have failed to present expert testimony, the documents at issue represent **.00657%** of the total document

production, and the information at issue is not vital to Plaintiffs' claims—would be *unprecedented*.

Further, permitting the ZHP Parties to withhold the documents at issue will have no bearing on Plaintiffs' ability to pursue their claims in this litigation. In stark contrast, ordering ZHP to produce these documents would put ZHP in the difficult position of having to decide whether to comply with U.S. laws and face potential criminal and civil penalties in China, or comply with Chinese laws and face sanctions from this Court for non-compliance with a discovery order.

Accordingly, for the reasons set forth herein, this Court should deny Plaintiffs' motion to compel.

Date: May 21, 2021

Respectfully submitted,

By: /s/ Seth A. Goldberg

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